

ROCKWELL MEDICAL TECHNOLOGIES INC

Form 10-Q

August 05, 2011

**Table of Contents**

**United States  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
Form 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended June 30, 2011**

**or**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File Number: 000-23661  
ROCKWELL MEDICAL TECHNOLOGIES, INC.**

(Exact name of registrant as specified in its charter)

Michigan

38-3317208

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

30142 Wixom Road, Wixom, Michigan

48393

(Address of principal executive offices)

(Zip Code)

(248) 960-9009

(Registrant's telephone number, including area code)  
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Edgar Filing: ROCKWELL MEDICAL TECHNOLOGIES INC - Form 10-Q

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). o  
Yes  No

APPLICABLE ONLY TO CORPORATE ISSUERS:

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding as of July 27, 2011
Common Stock, no par value	18,100,748 shares

---

**Rockwell Medical Technologies, Inc.**  
**Index to Form 10-Q**

	Page
<u>Part I Financial Information (unaudited)</u>	
<u>Item 1 Financial Statements (unaudited)</u>	
<u>Consolidated Balance Sheets</u>	3
<u>Consolidated Statements of Income</u>	4
<u>Consolidated Statements of Changes in Shareholders' Equity and Comprehensive Income (Loss)</u>	5
<u>Consolidated Statements of Cash Flows</u>	6
<u>Notes to Consolidated Financial Statements</u>	7
<u>Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	9
<u>Item 3 Quantitative and Qualitative Disclosures about Market Risk</u>	13
<u>Item 4 Controls and Procedures</u>	13
<u>Part II Other Information</u>	
<u>Item 1A Risk Factors</u>	14
<u>Item 6 - Exhibits</u>	14
<u>Signatures</u>	15
<u>Exhibit Index</u>	16
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</u>	
<u>EX-101 INSTANCE DOCUMENT</u>	
<u>EX-101 SCHEMA DOCUMENT</u>	
<u>EX-101 CALCULATION LINKBASE DOCUMENT</u>	
<u>EX-101 LABELS LINKBASE DOCUMENT</u>	
<u>EX-101 PRESENTATION LINKBASE DOCUMENT</u>	
<u>EX-101 DEFINITION LINKBASE DOCUMENT</u>	

**Table of Contents****PART I FINANCIAL INFORMATION****Item 1. Financial Statements**

**ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY  
CONSOLIDATED BALANCE SHEETS  
As of June 30, 2011 and December 31, 2010**

	<b>June 30, 2011 (unaudited)</b>	<b>December 31, 2010</b>
<b>ASSETS</b>		
Cash and Cash Equivalents	\$ 9,317,992	\$ 12,263,449
Investments Available for Sale	12,138,595	11,938,098
Accounts Receivable, net of a reserve of \$30,000 in 2011 and \$23,000 in 2010	4,497,143	4,507,296
Inventory	2,357,697	2,936,878
Other Current Assets	1,954,870	1,020,647
<b>Total Current Assets</b>	<b>30,266,297</b>	<b>32,666,368</b>
Property and Equipment, net	2,598,226	3,049,513
Intangible Assets	152,654	166,657
Goodwill	920,745	920,745
Other Non-current Assets	163,949	163,624
<b>Total Assets</b>	<b>\$ 34,101,871</b>	<b>\$ 36,966,907</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Capitalized Lease Obligations	\$ 11,891	\$ 18,215
Accounts Payable	3,218,790	3,659,507
Accrued Liabilities	3,000,480	2,577,022
Customer Deposits	141,540	165,476
<b>Total Current Liabilities</b>	<b>6,372,701</b>	<b>6,420,220</b>
Capitalized Lease Obligations	4,124	8,750
Shareholders Equity:		
Common Shares, no par value, 18,063,581 and 17,513,608 shares issued and outstanding	62,482,410	57,017,236
Common Share Purchase Warrants, 2,912,740 and 3,338,569 warrants issued and outstanding	7,406,685	8,275,509
Accumulated Deficit	(41,991,694)	(34,541,185)
Accumulated Other Comprehensive Loss	(172,355)	(213,623)
<b>Total Shareholders Equity</b>	<b>27,725,046</b>	<b>30,537,937</b>
<b>Total Liabilities And Shareholders Equity</b>	<b>\$ 34,101,871</b>	<b>\$ 36,966,907</b>

*The accompanying notes are an integral part of the consolidated financial statements.*

Table of Contents**ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY  
CONSOLIDATED INCOME STATEMENTS****For the three and six months ended June 30, 2011 and June 30, 2010**

(Unaudited)

	<b>Three Months Ended June 30, 2011</b>	<b>Three Months Ended June 30, 2010</b>	<b>Six Months Ended June 30, 2011</b>	<b>Six Months Ended June 30, 2010</b>
<b>Sales</b>	<b>\$ 11,802,307</b>	<b>\$ 15,506,712</b>	<b>\$ 25,093,094</b>	<b>\$ 30,486,664</b>
Cost of Sales	10,731,258	12,735,047	22,370,500	25,401,470
<b>Gross Profit</b>	<b>1,071,049</b>	<b>2,771,665</b>	<b>2,722,594</b>	<b>5,085,194</b>
Selling, General and Administrative	2,372,597	2,221,336	4,619,150	4,416,239
Research and Product Development	3,313,762	441,273	5,716,358	958,688
<b>Operating Income (Loss)</b>	<b>(4,615,310)</b>	<b>109,056</b>	<b>(7,612,914)</b>	<b>(289,733)</b>
Interest and Dividend Income	77,542	10,926	163,510	20,384
Interest Expense	504	3,065	1,105	7,414
Income (Loss) Before Income Taxes	(4,538,272)	116,917	(7,450,509)	(276,763)
Income Tax Expense				
<b>Net Income (Loss)</b>	<b>\$ (4,538,272)</b>	<b>\$ 116,917</b>	<b>\$ (7,450,509)</b>	<b>\$ (276,763)</b>
<b>Basic Earnings (Loss) per Share</b>	<b>\$ ( .26)</b>	<b>\$ .01</b>	<b>\$ ( .43)</b>	<b>\$ ( .02)</b>
<b>Diluted Earnings (Loss) per Share</b>	<b>\$ ( .26)</b>	<b>\$ .01</b>	<b>\$ ( .43)</b>	<b>\$ ( .02)</b>

*The accompanying notes are an integral part of the consolidated financial statements.*

**Table of Contents**

**ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY &**  
**COMPREHENSIVE INCOME (LOSS)**  
**For The Six Months Ended June 30, 2011**  
(Unaudited)

	COMMON SHARES		PURCHASE		ACCUMULATED	ACCUMULATED	SHAREHOLDER'S
			WARRANTS	AMOUNT		OTHER	
	SHARES	AMOUNT	WARRANTS	AMOUNT	DEFICIT	INCOME (LOSS)	EQUITY
Balance as of December 31, 2010	17,513,608	\$ 57,017,236	3,338,569	\$ 8,275,509	\$ (34,541,185)	\$ (213,623)	\$ 30,537,937
Net Loss					(7,450,509)		(7,450,509)
Unrealized Gains on Available-for-Sale Investments						41,268	41,268
Comprehensive Loss							(7,409,241)
Issuance of Common Shares	55,933	183,641					183,641
Issuance of Purchase Warrants			100,000	64,073			64,073
Exercise of Purchase Warrants	494,040	3,142,574	(525,829)	(932,897)			2,209,677
Stock Option Based Expense		1,832,153					1,832,153
Restricted Stock Amortization		306,806					306,806
Balance as of June 30, 2011	18,063,581	\$ 62,482,410	2,912,740	\$ 7,406,685	\$ (41,991,694)	\$ (172,355)	\$ 27,725,046

*The accompanying notes are an integral part of the consolidated financial statements.*



**Table of Contents****ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY  
CONSOLIDATED STATEMENTS OF CASH FLOWS****For the six months ended June 30, 2011 and June 30, 2010**

(Unaudited)

	<b>2011</b>	<b>2010</b>
Cash Flows From Operating Activities:		
Net (Loss)	<b>\$ (7,450,509)</b>	<b>\$ (276,763)</b>
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	650,695	707,749
Loss on Disposal of Assets	25,299	16,822
Share Based Compensation Non-employee Warrants	64,073	323,429
Share Based Compensation Employees	2,138,960	1,511,630
Changes in Assets and Liabilities:		
Decrease (Increase) in Accounts Receivable	10,153	(1,105,710)
Decrease in Inventory	579,181	224,891
(Increase) in Other Assets	(934,548)	(121,343)
Increase (Decrease) in Accounts Payable	(440,717)	53,134
Increase in Other Liabilities	399,522	356,439
Changes in Assets and Liabilities	(386,409)	(592,589)
Cash Provided By (Used) In Operating Activities	<b>(4,957,891)</b>	<b>1,690,278</b>
Cash Flows From Investing Activities:		
Purchase of Equipment	(210,704)	(509,432)
Proceeds on Sale of Assets		800
Purchase of Investments Available for Sale	(159,229)	
Cash Used In Investing Activities	<b>(369,933)</b>	<b>(508,632)</b>
Cash Flows From Financing Activities:		
Issuance of Common Shares	2,393,317	5,148
Payments on Notes Payable	(10,950)	(25,355)
Cash Provided By (Used) In Financing Activities	<b>2,382,367</b>	<b>(20,207)</b>
Increase (Decrease) In Cash and Cash Equivalents	(2,945,457)	1,161,439
Cash and Cash Equivalents at Beginning of Period	12,263,449	23,038,095
Cash and Cash Equivalents at End of Period	<b>\$ 9,317,992</b>	<b>\$ 24,199,534</b>

## Supplemental Cash Flow disclosure

	2011	2010
Interest Paid	\$ 1,105	\$ 7,414

*The accompanying notes are an integral part of the consolidated financial statements.*

**Table of Contents**

**Rockwell Medical Technologies, Inc. and Subsidiary**

**Notes to Consolidated Financial Statements**

**1. Description of Business**

Rockwell Medical Technologies, Inc. and Subsidiary (collectively, we, our, us, or the Company) manufacture, sell and distribute hemodialysis concentrates and other ancillary medical products and supplies used in the treatment of patients with End Stage Renal Disease, or ESRD. We supply our products to medical service providers who treat patients with kidney disease. Our products are used to cleanse patients' blood and replace nutrients lost during the kidney dialysis process. We primarily sell our products in the United States.

We are regulated by the Federal Food and Drug Administration under the Federal Drug and Cosmetics Act, as well as by other federal, state and local agencies. We have received 510(k) approval from the FDA to market hemodialysis solutions and powders. We also have 510(k) approval to sell our Dri-Sate Dry Acid Concentrate product line and our Dri-Sate Mixer.

We have obtained global licenses for certain dialysis related drugs which we are developing and seeking FDA approval to market. We plan to devote substantial resources to the development, testing and FDA approval of our lead drug candidate.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

Our consolidated financial statements include our accounts and the accounts for our wholly owned subsidiary, Rockwell Transportation, Inc. All intercompany balances and transactions have been eliminated in consolidation. The accompanying consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America, or GAAP, and with the instructions to Form 10-Q and Securities and Exchange Commission Regulation S-X as they apply to interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The balance sheet at December 31, 2010 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by GAAP for complete financial statements.

In the opinion of our management, all adjustments have been included which are necessary to make the financial statements not misleading. All of these adjustments that are material are of a normal and recurring nature. Our operating results for the three and six month periods ended June 30, 2011 are not necessarily indicative of the results to be expected for the year ending December 31, 2011. You should read our unaudited interim financial statements together with the financial statements and related footnotes for the year ended December 31, 2010 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 includes a description of our significant accounting policies.

**Revenue Recognition**

We recognize revenue at the time we transfer title to our products to our customers consistent with generally accepted accounting principles. Generally, we recognize revenue when our products are delivered to our customer's location consistent with our terms of sale. We recognize revenue for international shipments when title has transferred consistent with standard terms of sale.

We require certain customers, mostly international customers, to pay for product prior to the transfer of title to the customer. Deposits received from customers and payments in advance for orders are recorded as liabilities under Customer Deposits until such time as orders are filled and title transfers to the customer consistent with our terms of sale. At June 30, 2011 and December 31, 2010 we had customer deposits of \$141,540 and \$165,476, respectively.

**Table of Contents****Cash and Cash Equivalents**

We consider cash on hand, money market funds, unrestricted certificates of deposit and short term marketable securities with an original maturity of 90 days or less as cash and cash equivalents.

**Investments Available for Sale**

Investments Available for Sale are short-term investments, consisting principally of investments in short term duration bond funds, and are stated at fair value based upon observed market prices (Level 1 in the fair value hierarchy). Unrealized holding gains or losses on these securities are included in accumulated other comprehensive income (loss). Realized gains and losses, including declines in value judged to be other-than-temporary on available-for-sale securities are included as a component of other income or expense. There were no such realized gains or losses during the three and six months ended June 30, 2011 and June 30, 2010.

**Research and Product Development**

We recognize research and product development expenses as incurred. We incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products, including iron supplemented dialysate, aggregating approximately \$3.3 million and \$5.7 million for the three and six months ended June 30, 2011, respectively, and approximately \$0.4 million and \$1.0 million for the three and six months ended June 30, 2010, respectively.

We are conducting human clinical trials on iron supplemented dialysate and we recognize the costs of the human clinical trials as the costs are incurred and services performed over the duration of the trials.

**Net Earnings Per Share**

We computed our basic earnings (loss) per share using weighted average shares outstanding for each respective period. Diluted earnings per share also reflect the weighted average impact from the date of issuance of all potentially dilutive securities, consisting of stock options and common share purchase warrants, unless inclusion would have had an anti-dilutive effect. Actual weighted average shares outstanding used in calculating basic and diluted earnings per share were:

	<b>Three months ended June 30,</b>		<b>Six months ended June 30,</b>	
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>
Basic Weighted Average Shares Outstanding	17,575,673	17,086,723	17,441,426	17,069,297
Effect of Dilutive Securities		1,519,151		
Diluted Weighted Average Shares Outstanding	17,575,673	18,605,874	17,441,426	17,069,297

**3. Inventory**

Components of inventory as of June 30, 2011 and December 31, 2010 are as follows:

	<b>June 30, 2011</b>	<b>December 31, 2010</b>
Raw Materials	\$ 957,088	\$ 1,082,807
Work in Process	164,303	148,712
Finished Goods	1,236,306	1,705,359
Total	\$ 2,357,697	\$ 2,936,878

**4. Other Current Assets**

Other current assets includes amounts advanced to a contract services provider. These advances will offset future liabilities incurred with this service provider for services and travel related to our clinical trials. As of June 30, 2011, the amount included in other current assets was \$1.4 million.



**Table of Contents**

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements and the Notes thereto included elsewhere in this report. References in this report to we, our and us are references to Rockwell Medical Technologies, Inc. and its subsidiaries.

**Forward-Looking Statements**

We make forward-looking statements in this report and may make such statements in future filings with the Securities and Exchange Commission, or SEC. We may also make forward-looking statements in our press releases or other public or shareholder communications. Our forward-looking statements are subject to risks and uncertainties and include information about our expectations and possible or assumed future results of our operations. When we use words such as may, might, will, should, believe, expect, anticipate, estimate, continue, predict, intend, or similar expressions, or make statements regarding our intent, belief, or current expectations, we are making forward-looking statements. Our forward looking statements also include, without limitation, statements about our competitors, statements regarding the timing and costs of obtaining FDA approval of our new Soluble Ferric Pyrophosphate or SFP product and statements regarding our anticipated future financial condition, operating results, cash flows and business plans.

We claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 for all of our forward-looking statements. While we believe that our forward-looking statements are reasonable, you should not place undue reliance on any such forward-looking statements, which are based on information available to us on the date of this report or, if made elsewhere, as of the date made. Because these forward-looking statements are based on estimates and assumptions that are subject to significant business, economic and competitive uncertainties, many of which are beyond our control or are subject to change, actual results could be materially different. Factors that might cause such a difference include, without limitation, the risks and uncertainties discussed below and elsewhere in this report, and from time to time in our other reports filed with the Securities and Exchange Commission, including, without limitation, in Item 1A Risk Factors in our Form 10-K for the year ended December 31, 2010.

The dialysis provider market is highly concentrated in national and regional dialysis chains that account for the majority of our domestic revenue. Our business is substantially dependent on one of our customers that accounts for a significant portion of our sales. The loss of this customer would have a material adverse effect on our results of operations and cash flow.

We operate in a very competitive market against substantially larger competitors with greater resources.

Our new drug product requires FDA approval and expensive clinical trials before it can be marketed.

Even if our new drug product is approved by the FDA we may not be able to market it successfully.

We may not be successful in maintaining our gross profit margins.

We depend on government funding of healthcare.

Health care reform could adversely affect our business.

Orders from our international distributors may not result in recurring revenue.

We depend on key personnel.

**Table of Contents**

Our business is highly regulated.

We depend on contract research organizations and consultants to manage and conduct our clinical trials and if they fail to follow our protocol or meet FDA regulatory requirements our clinical trial data and results could be compromised causing us to delay our development plans or have to do more testing than planned.

Foreign approvals to market our new drug products may be difficult to obtain.

We may not have sufficient products liability insurance.

Our Board of Directors is subject to potential deadlock.

Shares eligible for future sale may affect the market price of our common shares.

The market price of our securities may be volatile.

Voting control and anti-takeover provisions reduce the likelihood that you will receive a takeover premium.

We do not anticipate paying dividends in the foreseeable future.

Other factors not currently anticipated may also materially and adversely affect our results of operations, cash flow and financial position. There can be no assurance that future results will meet expectations. We do not undertake, and expressly disclaim, any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as may be required by applicable law.

**Overview and Recent Developments**

Rockwell Medical operates in a single business segment as a specialty pharmaceutical company offering innovative products targeting end-stage renal disease, chronic kidney disease, and iron deficiency anemia. As an established manufacturer delivering high-quality hemodialysis concentrates to dialysis providers and distributors in the U.S. and abroad, we provide products used to maintain human life, remove toxins and replace critical nutrients in the dialysis patient's bloodstream.

We are currently developing unique, proprietary renal drug therapies. These exclusive renal drug therapies support disease management initiatives to improve the quality of life and care of dialysis patients and are designed to deliver safe and effective therapy, while decreasing drug administration costs and improving patient convenience and outcome. In July 2011, we acquired the right to manufacture and market in the United States a generic version of an injectable form of Vitamin -D (Calcitriol) for cash. We anticipate regulatory approval allowing us to begin marketing this drug around mid-2012 and our initial focus will be on marketing this drug to our current customers. We are not yet able to assess the potential impact on sales of this drug on our results of operations. Payment of the purchase price will not have a material impact on our liquidity or capital resources.

Our principal strategy is to develop high potential drug candidates while also expanding our dialysis products business. Our lead drug candidate SFP is a late-stage investigational drug designed to treat hemodialysis patients suffering from iron loss. SFP appears to provide clinical benefits compared to current treatment options and if approved for marketing has the potential to compete in the iron therapy market.

We could experience changes in our customer and product mix in future quarters that could impact gross profit, since we sell a wide range of products with varying profit margins and to customers with varying order patterns. These changes in mix have caused our gross profit and our gross profit margins to vary period to period. We anticipate continued increases in fuel and other costs in 2011 along with competitive pricing pressures in the renal market. The renewal of our supply arrangement with our largest customer in the first quarter of 2011 had no material impact on our results for the six months ended June 30, 2011 in comparison with the same period of the prior year.

**Table of Contents**

The majority of our business is with domestic clinics who order routinely. Certain major distributors of our products internationally have not ordered consistently resulting in significant fluctuation in our international sales from period to period. These international orders may increase in future periods or may not recur at all. For example, our largest international distributor did not place any orders in the second quarter of 2011 and currently is not expected to place orders during the remainder of 2011.

**Results of Operations for the Three and Six Months Ended June 30, 2011 and June 30, 2010****Sales**

Sales in the second quarter of 2011 were \$11.8 million compared to \$15.5 million in the second quarter of 2010. Sales decreased \$3.7 million or 23.9%, with international sales decreasing \$3.0 million or 75% and domestic sales decreasing \$0.7 million or 6.0% compared to the second quarter of 2010. Reduced purchase volumes from one international distributor accounted for all of the decrease in international sales. The domestic sales decrease was due to changes in product mix and, to a lesser extent, a loss of certain smaller chain accounts that were acquired by other chains for whom we do not supply products.

Sales for the first six months of 2011 decreased \$5.4 million or 17.7% to \$25.1 million compared to \$30.5 million in the first six months of 2010. International sales during the period decreased \$4.3 million or 55% to \$3.4 million, with reduced purchase volumes from a single distributor accounting for \$4.0 million of the decrease. Domestic sales decreased \$1.1 million or 5.0% in the first six months of 2011. Approximately \$0.7 million of the decrease was due to changes in product mix and to a lesser extent pricing pressures resulting from the implementation of the bundled reimbursement program by Medicare in 2011. Over the last year, customers have continued to convert to our Dri-Sate Dry Acid concentrate product line, which lowers providers' cost per treatment and reduces our sales, but improves our gross profit margins due to a reduction in shipping costs. Our Dri-Sate dry acid concentrate gallons increased to 56% of acid concentrate equivalent gallons from 44% in the first six months of 2010. The remainder of the decrease in domestic sales stemmed from the loss of certain smaller chain accounts that were acquired by other chains for whom we do not supply products.

**Gross Profit**

Gross profit in the second quarter of 2011 decreased \$1.7 million to \$1.1 million compared to \$2.8 million in the second quarter of 2010. Reduced sales volumes resulted in approximately \$0.8 million less in gross profit in the second quarter of 2011 compared to the second quarter of 2010. In the second quarter of 2011, we incurred inflationary cost increases for fuel, materials and labor aggregating \$0.7 million compared to the second quarter of 2010. Gross profit margin decreased to 9.1% compared to 17.9% in the second quarter of 2010.

Gross profit in the first six months of 2011 decreased \$2.4 million to \$2.7 million compared to \$5.1 million in the first six months of 2010. Approximately \$1.1 million of the decrease was due to the lower sales volumes, \$1.0 million was due to inflationary cost increases for fuel, material and labor and the remainder was attributable to lower sales due to product mix changes and sales incentives.

**Selling, General and Administrative Expense**

Selling, general and administrative expense ( SG&A ) during the second quarter of 2011 was \$2.4 million an increase of \$0.15 million or 6.8% over the second quarter of 2010. The majority of the increase was due to higher non-cash charges for equity compensation expense.

SG&A expense increased \$0.2 million or 4.6% to \$4.6 million in the first six months of 2011 compared to the first six months of 2010. All of the increase in SG&A was due to higher non-cash equity compensation expense,



## **Table of Contents**

which increased \$0.3 million while all other SG&A costs decreased \$0.1 million. Total non-cash charges for equity compensation aggregated \$2.1 million compared to \$1.8 million in the first six months of 2010.

### **Research and Development**

Research and development costs were \$3.3 million and \$0.4 million in the second quarter of 2011 and 2010, respectively. Research and development spending in the first six months of 2011 was \$5.7 million compared to \$1.0 million in the first six months of 2010. Spending in both years was primarily for development and approval of SFP, with the increase in 2011 due to the commencement of our Phase III clinical trials related to SFP.

### **Interest Income, Net**

Our net interest income was \$77,000 in the second quarter of 2011 compared to net interest income of \$8,000 in the second quarter of 2010. For the six months ending June 30, 2011 our net interest income was \$162,000 compared to \$13,000 in the first six months of 2011. These increases in net interest income were the result of higher yields on our investments.

### **Liquidity and Capital Resources**

Our strategy is centered on obtaining regulatory approval to market SFP and developing other high potential drug candidates, while also expanding our dialysis products business. We expect to expend substantial amounts in support of our clinical development plan and regulatory approval of SFP and its extensions and other product development opportunities. These initiatives will require the expenditure of substantial cash resources. We expect our cash needs for research and development spending to increase substantially in 2011 over 2010 as clinical development and patient testing activities increase for our Phase III clinical testing program for SFP. The timing and magnitude of such spending is largely dependent upon the initiation and pace of execution of the Phase III trials. We will invest in our Phase III clinical development program as well as other development initiatives over the next several years.

Our cash resources include cash generated from our business operations and the proceeds from our equity offering in 2009. Our current assets exceeded our current liabilities by \$23.9 million as of June 30, 2011 and included \$21.5 million in cash and short term investments. In the first six months of 2011, we used \$2.9 million in cash primarily to fund our research and development expenses of \$5.7 million. In the first six months of 2011, we received \$2.4 million from the exercise of warrants and stock options which funded a significant portion of our research and development expenditures. Cash increased \$0.6 million due to lower inventory levels and was partially offset by a \$0.4 million reduction in accounts payable. Other current assets increased \$0.9 million during 2011, with the increase due to advances to a service provider to be offset against future services. Those advances aggregated \$1.4 million as of June 30, 2011.

We believe our current and prospective sources of cash resources will be sufficient to complete the SFP testing and FDA approval process and to fund our other anticipated research and development activities and ordinary course operating cash requirements in 2011 and 2012. We expect to generate positive cash flow from operations in 2011, excluding the effect of our research and development expenses. In addition, we may continue to realize substantial cash proceeds from warrants that expire in each of the next two years.

The cost to obtain regulatory approval for a drug in the United States is expensive and can take several years. If we use more cash than anticipated for SFP development, or are required to do more testing than expected, or if the assumptions underlying our cash flow projections prove to be incorrect and our core business does not generate cash flow as we anticipate, or if we pursue opportunities to expand our business, we may need to obtain additional cash, such as through equity financing, debt financing of capital expenditures or a line of credit, to supplement our working capital. We explore opportunities from time to time to increase our cash resources, to reduce our liquidity risk and to have resources available to permit us to pursue expansion opportunities. Alternatively, we may seek to enter into product development arrangements with an international partner in order to fully execute our strategic plan. We may also evaluate alternative sources of business development funding, licensing agreements with

**Table of Contents**

international marketing partners, sub-licensing of certain products for certain markets and other potential funding sources.

**Item 3. Quantitative and Qualitative Disclosures about Market Risk**

**Interest Rate Risk**

Our current exposure to interest rate risk is limited to changes in interest rates on short term investments of cash. As of June 30, 2011, we had \$12.1 million invested in short term bond funds which typically yield higher returns than the interest realized in money market funds. While these funds hold bonds of short term duration, their market value is affected by changes in interest rates. Increases in interest rates will reduce the market value of bonds held in these funds and we may incur unrealized losses from the reduction in market value of the fund. If we liquidate our position in these funds, those unrealized losses may result in realized losses which may or may not exceed the interest and dividends earned from those funds. However, due to the short duration of these short term bond fund portfolios, we do not believe that a hypothetical 100 basis point increase or decrease in interest rates will have a material impact on the value of our investment portfolio.

**Foreign Currency Exchange Rate Risk**

Our international business is conducted in U.S. dollars. It has not been our practice to hedge the risk of appreciation of the U.S. dollar against the predominant currencies of our trading partners. We have no significant foreign currency exposure to foreign supplied materials, and an immediate 10% strengthening or weakening of the U.S. dollar would not have a material impact on our shareholders' equity or net income.

**Item 4. Controls and Procedures**

**Disclosure Controls and Procedures**

Management is responsible for establishing and maintaining effective disclosure controls and procedures, as defined under Rule 13a-15 of the Securities Exchange Act of 1934, as amended, that are designed to ensure that material information required to be disclosed in our reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required financial disclosure. In designing and evaluating the disclosure controls and procedures, we recognized that a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As of the end of the period covered by this report, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, as of the end of the period covered by this report.

**Table of Contents**

**Changes in Internal Control over Financial Reporting**

No changes were made to our internal control over financial reporting (as defined in Rule 13a-15 under the Exchange Act) during the fiscal quarter ended June 30, 2011 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II OTHER INFORMATION**

**Item 1A. Risk Factors**

For information regarding risk factors affecting us, see Risk Factors in Item 1A of Part I of our 2010 Annual Report on Form 10-K. There have been no material changes to the risk factors described in such Form 10-K.

**Item 6. Exhibits**

See Exhibit Index following the signature page, which is incorporated herein by reference.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**ROCKWELL MEDICAL  
TECHNOLOGIES, INC.**

(Registrant)

Date: August 5, 2011

/s/ ROBERT L. CHIOINI  
Robert L. Chioini  
President and Chief Executive Officer  
(principal executive officer) (duly  
authorized officer)

Date: August 5, 2011

/s/ THOMAS E. KLEMA  
Thomas E. Klema  
Vice President and Chief Financial Officer  
(principal financial officer and principal  
accounting officer)

15

---

**Table of Contents**

**10-Q EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
10.41	Amended and Restated Rockwell Medical Technologies, Inc. 2007 Long Term Incentive Plan (Company's definitive Proxy Statement filed April 15, 2011).
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1	Certification pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(b) of the Securities Exchange Act of 1934
101.INS	* XBRL Instance Document
101.SCH	* XBRL Taxonomy Extension Schema
101.CAL	* XBRL Taxonomy Extension Calculation Linkbase
101.DEF	* XBRL Taxonomy Extension Definition Database
101.LAB	* XBRL Taxonomy Extension Label Linkbase
101.PRE	* XBRL Taxonomy Extension Presentation Linkbase

\* XBRL (Extensible Business Reporting Language) information is furnished and not filed herewith, is not a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.